

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 18, 2018

Findings Date: December 18, 2018

Project Analyst: Julie M. Faenza

Assistant Chief: Lisa Pittman

Project ID #: F-11592-18

Facility: Renaissance Park Dialysis

FID #: 180264

County: Mecklenburg

Applicant: Renal Treatment Centers – Mid-Atlantic, Inc.

Project: Develop a new 10-station dialysis facility by relocating 10 existing dialysis stations from Charlotte Dialysis and offer training for home peritoneal dialysis

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

Renal Treatment Centers – Mid-Atlantic, Inc. (RTC) d/b/a Renaissance Park Dialysis (RPD) proposes to develop a new 10-station dialysis facility by relocating 10 existing dialysis stations from Charlotte Dialysis. The applicant also proposes to offer training and support for home peritoneal dialysis (PD) patients.

Need Determination

The applicant does not propose to increase the number of licensed beds in any category, add any new health services, or acquire equipment for which there is a need determination in the 2018 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2018 SMFP that are applicable to this review.

Policies

There are two policies in the 2018 SMFP which are applicable to this review:

Policy ESRD-2: Relocation of Dialysis Stations, on page 27 of the 2018 SMFP, states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 2. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

RPD’s proposed location and Charlotte Dialysis are both located in Mecklenburg County. Therefore, the application is consistent with Policy ESRD-2.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 33 of the 2018 SMFP, states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be

consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

The projected capital cost for the proposed project is greater than \$2 million but less than \$5 million. In Section B, pages 12-13, the applicant provides a written statement describing the project's plan to assure improved energy efficiency and water conservation. The applicant provides examples of energy efficient and water conservation features it will include in the proposed facility and states that it is implementing strategies to promote energy conservation, water conservation, paper conservation, and waste reduction.

The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

RTC proposes to develop a new 10-station dialysis facility, RPD, by relocating 10 existing dialysis stations from Charlotte Dialysis. RTC also proposes to provide training and support for PD patients, but does not propose to provide training and support for home hemodialysis patients.

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations as "...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area." Thus,

the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

The following table illustrates projected patient origin.

RPD Patients by County						
	Operating Year 1 – CY 2021			Operating Year 2 – CY 2022		
County	# of IC* Patients	# of PD Patients	% of Total	# of IC* Patients	# of PD Patients	% of Total
Mecklenburg	33	2	100%	34	3	100%
Total	33	2	100%	34	3	100%

*IC = In-Center

Source: Section C, page 14.

In Section C, pages 14-16, the applicant provides the assumptions and methodology it used to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 16-17, the applicant states that due to the number of patients living in southwestern Mecklenburg County, the patients would be best served by the addition of a new facility in that area. Additionally, the applicant projects the 10-station facility to have a utilization rate of 3.3 patients per station per week, or 82.5 percent, by the end of the first operating year. The projected utilization exceeds the minimum operating standard of 3.2 patients per station per week as promulgated in 10A NCAC 14C .2203(b).

On page 16, the applicant states that patients are receiving more education about the dialysis modality that is most appropriate, and The Centers for Medicare and Medicaid Services (CMS) are encouraging providers to increase the number of PD patients to 50 percent of the total ESRD population within the next few years.

The information is reasonable and adequately supported for the following reasons:

- The applicant provides letters of support from 40 current Mecklenburg County patients who state that they will consider transferring their care to the new facility based on convenience or location.
- The applicant reasonably projects that the utilization rate of the new facility will be 3.3 patients per station per week at the end of operating year one, which exceeds the required minimum operating standard promulgated in 10A NCAC 14C .2203(b), based on the growth of the patient population using the Mecklenburg County Five Year Average Annual Change Rate (AACR) of 3.9 percent as published in the July 2018 Semiannual Dialysis Report (SDR).
- The applicant provides reasonable and adequately supported information regarding reasons for increased utilization of PD services by patients.

Projected Utilization

In Section C, page 14, the applicant provides projected utilization as illustrated in the following table.

RPD Projected Utilization						
	Operating Year 1 – CY 2021			Operating Year 2 – CY 2022		
County	# of IC* Patients	# of PD Patients	% of Total	# of IC Patients	# of PD Patients	% of Total
Mecklenburg	33	2	100%	34	3	100%
Total	33	2	100%	34	3	100%

*IC = In-Center

In Section C, pages 14-16, the applicant provides the assumptions and methodology it used to project in-center and PD patient utilization, which are summarized below.

In-Center

- The applicant begins its utilization projections with the 40 Mecklenburg County patients who have signed letters of support stating that they would consider transferring care to the proposed facility based on convenience.
- The applicant assumes that 32 of those 40 patients will transfer their care to RPD once it opens.
- The applicant assumes that the Mecklenburg County patient population will increase annually at a rate of 3.9 percent, consistent with the Mecklenburg County Five Year AACR published in the July 2018 SDR.
- The project is scheduled for completion on January 1, 2021. OY1 is CY 2021. OY2 is CY 2022.

In Section C, page 15, the applicant provides the calculations it used to arrive at the projected patient census for OY1 and OY2, as summarized in the table below.

RPD In-Center Patients	
Starting point of calculations is the 32 Mecklenburg County patients projected to transfer care to RPD. This is the patient census on January 1, 2021 and the starting census for this project.	32
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR of 3.9%. This is the projected census on December 31, 2021 (end of OY1).	$32 \times 1.039 = 33.248$
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the Five Year AACR of 3.9%. This is the projected census on December 31, 2022 (end of OY2).	$33.248 \times 1.039 = 34.5447$

The applicant rounds down and projects to serve 33 patients on 10 stations, which is 3.3 patients per station per week ($33 \text{ patients} / 10 \text{ stations} = 3.3$), by the end of OY1 and 34 patients

on 10 stations, which is 3.4 patients per station per week (34 patients / 10 stations = 3.4), by the end of OY2. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Home Peritoneal Dialysis Patients

- The applicant begins its utilization projections with the two Mecklenburg County PD patients who have signed letters of support stating that they would consider transferring care to the proposed facility based on convenience or location.
- The applicant assumes that one patient will transfer care to RPD once it opens.
- The applicant assumes that the PD patient population will grow at a rate of one patient per year.
- The project is scheduled for completion on January 1, 2021. OY1 is CY 2021. OY2 is CY 2022.

In Section C, page 16, the applicant provides the calculations it used to arrive at the projected patient census for OY1 and OY2, as summarized in the table below.

RPD PD Patients	
Starting point of calculations is the one Mecklenburg County PD patient projected to transfer care to RPD. This is the patient census on January 1, 2021 and the starting census for this project.	1
The PD patient population is projected forward by one year to December 31, 2021, using a growth rate of one patient per year. This is the projected census on December 31, 2021 (end of OY1).	1 + 1 = 2
The PD patient population is projected forward by one year to December 31, 2022, using a growth rate of one patient per year. This is the projected census on December 31, 2022 (end of OY2).	2 + 1 = 3

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant projects future utilization based on patient letters of support.
- The applicant uses the Five Year AACR for Mecklenburg County as published in the July 2018 SDR to project in-center patient utilization.
- The applicant's projected growth of the PD patient population is based on reasonable and adequately supported information.
- The applicant's projected in-center patient utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Access

In Section C, page 17, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

We will make every reasonable effort to accommodate all patients, especially those with special needs such as the handicapped, patients attending school or patients who work.

...

Payment will not be required upon admission. Therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

In Section L, page 48, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

RPD Projected Payor Mix CY 2022			
Payment Source	% Total Patients	% In-Center Patients	% PD Patients
Medicare	26.9%	27.0%	26.5%
Medicaid	3.8%	4.9%	0.0%
Commercial Insurance	12.2%	10.7%	17.6%
Medicare/Commercial	29.5%	25.4%	44.1%
Medicare/Medicaid	24.4%	29.5%	5.9%
Misc. (including VA)	3.2%	2.5%	5.9%
Total	100.0%	100.0%	100.0%

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.

- Projected utilization is reasonable and adequately supported.
 - The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

RTC proposes to develop a new 10-station dialysis facility, RPD, by relocating 10 existing dialysis stations from Charlotte Dialysis.

According to the July 2018 SDR, Charlotte Dialysis had 36 certified stations as of December 31, 2017. In projects that were previously approved but undeveloped as of December 31, 2017, Charlotte Dialysis was approved to relocate 10 dialysis stations to Brookshire Dialysis and to add 8 stations:

- Project I.D. #F-11109-15 (relocate 10 stations to Brookdale Dialysis) – certified as of June 30, 2018
- Project I.D. #F-11155-16 (add 8 stations) – certified as of July 2, 2018

As of the date of these findings, Charlotte Dialysis has 34 certified stations. The applicant proposes to relocate 10 stations to develop RPD, which will leave Charlotte Dialysis with 24 stations upon project completion.

In Section D, page 24, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated, or relocated will be adequately met following completion of the project. On page 24, the applicant states:

“Given this projected growth of the in-center patient population, additional Certificate of Need application(s) will be submitted based on facility need as the facility approaches full capacity of stations to ensure that the needs of the facility’s patients will continue to be met. Once the ten stations are transferred to Renaissance Park Dialysis, Charlotte Dialysis will have space in the existing facility for twelve stations.” (emphasis in original)

In Section D, page 24, the applicant provides projected utilization of Charlotte Dialysis following completion of the proposed project, as shown in the table below.

Charlotte Dialysis Projected Utilization		
	CY 2021	CY 2022
# Patients	109	114

In Section D, pages 23-24, the applicant provides the assumptions and methodology used to project utilization, as discussed below.

- The applicant states that there were 124 patients dialyzing at Charlotte Dialysis on December 31, 2017. 119 of those patients were Mecklenburg County residents and 5 patients are from other counties.
- The applicant projects that the Mecklenburg County patient population of Charlotte Dialysis will grow at a rate of 3.9 percent, which is the Five Year AACR for Mecklenburg County as published in the July 2018 SDR.
- The applicant projects no growth for patients residing outside of Mecklenburg County, but adds those patients to the calculations where appropriate.
- The applicant states that it projects 32 patients from Charlotte Dialysis will transfer care to RPD once it opens and subtracts those 32 patients from the calculations where appropriate.

In Section D, page 24, the applicant provides the calculations it used to arrive at the projected patient census for Charlotte Dialysis during OY1 and OY2 of the proposed project, as summarized in the table below.

Charlotte Dialysis Patients	
Starting point of calculations is the 119 Mecklenburg County patients dialyzing at Charlotte Dialysis on December 31, 2017, and is the starting census for this project.	119
Mecklenburg County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR of 3.9%.	$119 \times 1.039 = 123.641$
Mecklenburg County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR of 3.9%.	$123.641 \times 1.039 = 128.462$
Mecklenburg County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR of 3.9%.	$128.462 \times 1.039 = 133.472$
The 32 patients projected to transfer care to RPD upon project completion are subtracted from the Mecklenburg County patient population dialyzing at Charlotte Dialysis.	$133.472 - 32 = 101$
The patients from other counties are added. This is the projected census at the start of OY1.	$101 + 5 = 106$
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR of 3.9%.	$101 \times 1.039 = 104.939$
The patients from other counties are added. This is the projected census on December 31, 2021 (end of OY1).	$104.939 + 5 = 109.939$
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the Five Year AACR of 3.9%.	$104.939 \times 1.039 = 109.031$
The patients from other counties are added. This is the projected census on December 31, 2022 (end of OY2).	$109.031 + 5 = 114.031$

The applicant rounds down and projects to serve 109 patients on 24 stations, which is 4.54 patients per station per week ($109 \text{ patients} / 24 \text{ stations} = 4.54$), for a utilization rate of 113.5 percent by the end of OY1, and 114 patients on 24 stations, which is 4.75 patients per station per week ($114 \text{ patients} / 24 \text{ stations} = 4.75$), for a utilization rate of 118.8 percent, by the end of OY2. On page 24, the applicant states that it will submit applications for more stations based on facility need as the patient population increases, and states that once the ten stations that are the subject of this application are relocated to RPD, Charlotte Dialysis will have room to backfill 12 stations.

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant uses the Five Year AACR for Mecklenburg County as published in the July 2018 SDR to project in-center patient utilization.
- The applicant accounts for patients who are proposed to transfer care to a different facility as part of projects under development.

In Section D, page 24, the applicant states that the proposed relocation of stations will have no effect on the ability of patients using the existing facility, including low income patients, women, disabled patients, and other underserved patients, to access services, and states that it makes dialysis services available to all residents of the service area without qualification.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated, or relocated will be adequately met following project completion.
 - The project will not adversely impact the ability of underserved groups to access these services following project completion.
- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

RTC proposes to develop a new 10-station dialysis facility, RPD, by relocating 10 existing dialysis stations from Charlotte Dialysis.

In Section E, page 25, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- **Maintain the Status Quo:** The applicant states that due to the growth rate of the in-center patient population that resides in the identified area of Mecklenburg County, this is not an effective alternative.
- **Locate the Facility in a Different Area of Mecklenburg County:** The applicant states that based on the location of the patients who provided letters of support in Exhibit C-1, and based on geographic access, developing the facility in a different part of Mecklenburg County is not an effective alternative.

On pages 25-26, the applicant states that its proposal is the most effective alternative because it meets the need of the growing patient population specific to the proposed location of the new facility.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Renal Treatment Centers – Mid-Atlantic, Inc. d/b/a Renaissance Park Dialysis shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Policy ESRD-2, Renal Treatment Centers – Mid-Atlantic, Inc. d/b/a Renaissance Park Dialysis shall develop a new kidney disease treatment center to be known as Renaissance Park Dialysis by relocating no more than 10 dialysis stations from Charlotte Dialysis.**
 - 3. Upon completion of this project, DaVita, Inc. shall take the necessary steps to decertify 10 dialysis stations at Charlotte Dialysis for a total of no more than 24 dialysis stations at Charlotte Dialysis.**
 - 4. Renal Treatment Centers – Mid-Atlantic, Inc. d/b/a Renaissance Park Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

RTC proposes to develop a new 10-station dialysis facility, RPD, by relocating 10 existing dialysis stations from Charlotte Dialysis.

Capital and Working Capital Costs

In Section F, page 27, the applicant projects the total capital cost of the project, as shown in the table below.

Construction and Site Preparation Costs	\$1,439,166
Architect and Engineering Fees	\$166,000
Medical Equipment	\$362,620
Non-Medical Equipment	\$350,916
Miscellaneous Costs	\$44,260
Total	\$2,362,962

In Section F, pages 29-30, the applicant projects that start-up costs will be \$198,078 and initial operating expenses will be \$813,999 for a total working capital of \$1,012,077. On pages 29-30, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F, pages 28 and 31, the applicant states that it will fund both the capital and working capital costs of the proposed project with accumulated reserves. Exhibit F-5 contains a letter from the applicant on behalf of the Chief Accounting Officer of DaVita, Inc. (DaVita), DVA’s parent company, authorizing the use of accumulated reserves for the capital needs of the project. Exhibit F-7 contains a Form 10-K Consolidated Financial Statement from DaVita, which showed that as of December 31, 2017, DaVita had adequate cash and assets to fund the capital cost of the proposed project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

Projected Revenues and Operating Expenses		
RPD	Operating Year 1 CY 2021	Operating Year 2 CY 2022
Total Treatments	5,039	5,336
Total Gross Revenues (Charges)	\$1,715,347	\$1,826,268
Total Net Revenue	\$1,652,589	\$1,759,824
Average Net Revenue per Treatment	\$328	\$330
Total Operating Expenses (Costs)	\$1,627,998	\$1,699,573
Average Operating Expense per Treatment	\$323	\$319
Net Income/Profit	\$24,591	\$60,251

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

RTC proposes to develop a new 10-station dialysis facility, RPD, by relocating 10 existing dialysis stations from Charlotte Dialysis.

On page 365, the 2018 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

According to Table B of the July 2018 SDR, there are 23 existing or approved dialysis facilities in Mecklenburg County, 17 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the July 2018 SDR, is provided below:

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2017				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Brookshire Dialysis*	DaVita	Charlotte	0	0.00%
Charlotte Dialysis	DaVita	Charlotte	36	86.11%
Charlotte East Dialysis	DaVita	Charlotte	34	90.44%
Huntersville Dialysis	DaVita	Huntersville	14	83.93%
Mint Hill Dialysis	DaVita	Mint Hill	16	84.38%
North Charlotte Dialysis Center	DaVita	Charlotte	37	68.24%
South Charlotte Dialysis**	DaVita	Charlotte	23	83.70%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis*	DaVita	Charlotte	0	0.00%
BMA Beatties Ford	BMA	Charlotte	32	89.84%
BMA Nations Ford	BMA	Charlotte	28	91.96%
BMA of East Charlotte	BMA	Charlotte	26	88.46%
BMA of North Charlotte	BMA	Charlotte	40	98.75%
BMA West Charlotte	BMA	Charlotte	29	87.93%
Carolinas Medical Center	CMC	Charlotte	9	25.00%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	69.79%
DSI Glenwater Dialysis	DSI	Charlotte	42	75.00%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
FKC Regal Oaks	BMA	Charlotte	12	43.75%
FKC Southeast Charlotte*	BMA	Charlotte	0	0.00%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
FMC Charlotte	BMA	Charlotte	44	89.20%
FMC Matthews	BMA	Matthews	21	115.48%
FMC Southwest Charlotte	BMA	Charlotte	13	84.62%

Source: July 2018 SDR, Table B.

* Facility under development.

**Per Project I.D. #F-11323-17, this facility is being relocated to a new location.

In Section G, page 33, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Mecklenburg County. The applicant states:

“As of December 31, 2017 there were 23 existing and approved dialysis facilities in Mecklenburg County with a total of 480 certified stations. This certificate of need application does not propose to increase the number of stations in Mecklenburg County. Transferring ten stations from Charlotte Dialysis will create a new facility at a different location to better serve patients living in the area of the new facility, but it will not result in the duplication of existing services.”

The applicant adequately demonstrates that the proposal will not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant does not propose to add additional stations to Mecklenburg County.
- The applicant adequately demonstrates the need the population proposed to be served has for the proposed new facility and adequately demonstrates that the facility will be

appropriately utilized. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section H, page 34, the applicant provides projected staffing for the proposed services, as illustrated in the following table.

RPD Projected Staffing	
	# FTE Staff
Registered Nurses	2.0
Patient Care Technician	4.0
Administrator	1.0
Dietician	0.5
Social Worker	0.5
Home Training RN	0.5
Administrative Assistant	1.0
Biomed Technician	0.5
TOTAL	10.0

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H, pages 35-36, the applicant describes the methods used to recruit or fill new positions and its proposed training and continuing education programs. The applicant provides supporting documentation in Exhibits H-2, H-3, and H-4. In Section H, page 35, the applicant identifies the proposed medical director, Dr. Michael Boswell, and states that Dr. Boswell is board certified in nephrology. Comments submitted during the public comment period suggest that Dr. Boswell is not board certified in nephrology, but instead board certified in internal medicine, and suggests that the lack of board certification in nephrology is cause to find the application nonconforming to this criterion. However, CMS regulations and guidelines state that the medical director for a dialysis treatment facility may be certified in nephrology, pediatric nephrology, internal medicine, or general pediatrics, providing the doctor has completed an appropriate training program in nephrology and has at least a year's experience in treating nephrology patients. The

onus is on the dialysis facility to maintain the appropriate certifications. Additionally, CMS regulations and guidelines state that if a physician meeting those requirements is unavailable, another physician may serve as medical director subject to approval from the Secretary of DHHS. According to the North Carolina Medical Board, Dr. Boswell is board certified in internal medicine, and completed a fellowship in nephrology at a hospital in Ohio in 2006. In Exhibit I-3, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services. The comments submitted during the public comment period provide no information to suggest that Dr. Boswell is not appropriately credentialed to serve as medical director of the proposed facility.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I, page 38, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

RPD – Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	On site
Self-care training (in-center)	On site
Home training	
HH	Charlotte East Dialysis
PD	On site
Accessible follow-up program	On site
Psychological counseling	On site
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	Atrium Health
Emergency care	Atrium Health
Blood bank services	Atrium Health
Diagnostic and evaluation services	Atrium Health
X-ray services	Atrium Health
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	Atrium Health
Vascular surgery	Atrium Health
Transplantation services	Atrium Health
Vocational rehabilitation & counseling	NC DHHS Vocational Rehab Services
Transportation	Mecklenburg Transportation System

The applicant provides supporting documentation in Exhibits I-1 and I-2.

In Section I, pages 39-40, the applicant describes its proposed relationships with other local health care and social service providers.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

RTC proposes to develop a new 10-station dialysis facility, RPD, by relocating 10 existing dialysis stations from Charlotte Dialysis.

In Section K, page 43, and Exhibit K-1(a), the applicant states that the project involves constructing 11,273 square feet of new space to house the proposed facility, including 6,467 square feet of treatment area. Line drawings are provided in Exhibit K-1(a). Comments submitted during the public comment period suggest that the proposed facility is too large for the number of stations it proposes to relocate, and therefore does not demonstrate that the cost, design, and means of construction proposed will not unduly increase costs. The Project Analyst

notes that there is no applicable administrative rule or statutory criterion requiring an applicant to propose a specific number of square feet for a proposed facility in order to meet the requirements of this statutory criterion, and that the applicant adequately demonstrates conformity to this and all other statutory review criteria.

In Section K, page 42, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

In Section K, pages 43-46, the applicant identifies the proposed primary and secondary sites, provides information about the availability of the sites and zoning and special use permits, and provides supporting documentation in Exhibits K-4(d), K-4(g), K-4(h), and K-5(h). Comments submitted during the public comment period suggest that the applicant has budgeted an inadequate amount of money for the purchase of the primary site, due to its listed tax value in municipal tax records. The Project Analyst notes that in Exhibit K-4(h), the applicant provides a letter documenting the listed sale price of the primary site, and the comments submitted during the public comment period provide no basis for discounting the letter submitted by the applicant in Exhibit K-4(h).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 51, the applicant provides the historical payor mix during CY 2017 for Charlotte Dialysis, as shown in the table below.

Charlotte Dialysis Historical Payor Mix CY 2017	
Payment Source	% Total Patients
Medicare	27.0%
Medicaid	4.9%
Commercial Insurance	10.7%
Medicare/Commercial	25.4%
Medicare/Medicaid	29.5%
Misc. (including VA)	2.5%
Total	100.00%

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant’s service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Mecklenburg	11%	52%	53%	12%	6%	12%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table>; Latest Data 7/1/17 as of 7/17/18

*Excludes "White alone" who are "not Hispanic or Latino"

**"Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina’s based on the Network’s recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

¹<https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, the applicant states in Section L, page 50, that it has no obligation by any of its facilities to provide uncompensated care or community service under any federal regulations.

In Section L, page 50, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 48, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

RPD Projected Payor Mix CY 2022			
Payment Source	% Total Patients	% In-Center Patients	% PD Patients
Medicare	26.9%	27.0%	26.5%
Medicaid	3.8%	4.9%	0.0%
Commercial Insurance	12.2%	10.7%	17.6%
Medicare/Commercial	29.5%	25.4%	44.1%
Medicare/Medicaid	24.4%	29.5%	5.9%
Misc. (including VA)	3.2%	2.5%	5.9%
Total	100.0%	100.0%	100.0%

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 84.6 percent of all patients will have some or all of their services covered by Medicare and/or Medicaid.

On page 48, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The projected payor mix is based on the historical payor mix for facilities owned and/or operated by the applicant in Mecklenburg County.
- Projected utilization is reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, page 50, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M, page 52, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

RTC proposes to develop a new 10-station dialysis facility, RPD, by relocating 10 existing dialysis stations from Charlotte Dialysis.

On page 365, the 2018 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

According to Table B of the July 2018 SDR, there are 23 existing or approved dialysis facilities in Mecklenburg County, 17 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the July 2018 SDR, is provided below:

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2017				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
Brookshire Dialysis*	DaVita	Charlotte	0	0.00%
Charlotte Dialysis	DaVita	Charlotte	36	86.11%
Charlotte East Dialysis	DaVita	Charlotte	34	90.44%
Huntersville Dialysis	DaVita	Huntersville	14	83.93%
Mint Hill Dialysis	DaVita	Mint Hill	16	84.38%
North Charlotte Dialysis Center	DaVita	Charlotte	37	68.24%
South Charlotte Dialysis**	DaVita	Charlotte	23	83.70%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis*	DaVita	Charlotte	0	0.00%
BMA Beatties Ford	BMA	Charlotte	32	89.84%
BMA Nations Ford	BMA	Charlotte	28	91.96%
BMA of East Charlotte	BMA	Charlotte	26	88.46%
BMA of North Charlotte	BMA	Charlotte	40	98.75%
BMA West Charlotte	BMA	Charlotte	29	87.93%
Carolinas Medical Center	CMC	Charlotte	9	25.00%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	69.79%
DSI Glenwater Dialysis	DSI	Charlotte	42	75.00%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
FKC Regal Oaks	BMA	Charlotte	12	43.75%
FKC Southeast Charlotte*	BMA	Charlotte	0	0.00%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
FMC Charlotte	BMA	Charlotte	44	89.20%
FMC Matthews	BMA	Matthews	21	115.48%
FMC Southwest Charlotte	BMA	Charlotte	13	84.62%

Source: July 2018 SDR, Table B.

* Facility under development.

**Per Project I.D. #F-11323-17, this facility is being relocated to a new location.

In Section N, page 53, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area

will promote the cost-effectiveness, quality, and access to the proposed services. On page 53, the applicant states:

“The development of Renaissance Park Dialysis will have no effect on any dialysis facilities located in Mecklenburg County or in counties contiguous to it. ...

The proposed facility will not have an adverse effect on competition since the patients already being served by DaVita will be transferring their care from one DaVita facility to another DaVita facility, which will be more convenient for the patients who have indicated this in the letters they signed. ...

The bottom line is Renaissance Park Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Exhibit A-11, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 104 dialysis facilities located in North Carolina.

In Section O, page 54, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two of these facilities. Supporting documentation is provided in Exhibit O-3. The applicant states that all of the problems have been corrected. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 104 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-C- In Section C, page 14, the applicant projects that RPD will serve 33 patients on 10 stations, or a rate of 3.3 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the*

need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

- NA- RPD is not an existing facility. Therefore, this Rule is not applicable to this review.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C, pages 14-16, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.